

## Claims

What is claimed is:

1. A disposable cassette for supplying a heat exchange fluid to a heat exchange catheter, said cassette comprising:

5                    an external heat exchanger comprising a flow channel having an inlet and an outlet;

                  a first fluid supply line, said first fluid supply line in fluid communication with said flow channel inlet;

10                   a pump head contained in the disposable fluid supply cassette, said pump head having a pump inlet and a pump outlet, said pump inlet in fluid communication with said external heat exchanger flow channel outlet for pumping fluid from said flow channel outlet;

                  a second fluid supply line, said second fluid supply line in fluid communication with said pump outlet for receiving fluid pumped out of said pump outlet; and

15                   a pressure regulator, said pressure regulator in fluid communication with said pump outlet for regulating the pressure of fluid pumped from said pump.

2. The cassette of Claim 1 wherein said external heat exchanger comprises a structural member and a compliant member, said compliant member being sealed to said structural member in a pattern, said pattern forming a flow channel between said compliant member and said structural member.
3. The cassette of Claim 1 wherein first and second fluid supply lines are connected through a heat exchange catheter thereby creating a fluid circuit including said external heat exchanger, said pump, said first and second fluid lines, and said catheter.
4. The cassette of Claim 1 wherein said pressure regulator is a regulator valve.
- 25 5. The cassette of Claim 4 wherein said pressure regulator further comprises a pressure regulator chamber adjacent to a sensing chamber which communicates with the pressure regulator valve.
6. The cassette of Claim 5 wherein said pressure regulator chamber comprises a counter spring and a counter spring block.



- 7. The cassette of Claim 5 wherein said sensing chamber comprises a diaphragm and a push rod.
- 8. The cassette of Claim 1 wherein said pressure regulator is a pressure damper.
- 9. The cassette of Claim 8 wherein said pressure damper is a compressible material.
- 5 10. The cassette of Claim 9 wherein said compressible material is a block of foam.
- 11. The cassette of Claim 10 wherein said foam is enclosed with a sealed plastic pouch.
- 12. The cassette of Claim 10 wherein said foam is coated with plastic or silicone.
- 13. The cassette of Claim 9 wherein said compressible material is a gas encapsulated within a flexible pouch.
- 10 14. A heat exchange fluid supply system for a heat exchange catheter, said system comprising:
  - an external heat exchanger comprising a structural member and a compliant member, said compliant member sealed to said structural member in a pattern, said pattern forming a flow channel between said compliant member and said structural member; said flow channel having an inlet and an outlet;
  - 15 a first fluid supply line, said first fluid supply line in fluid communication with said flow channel inlet;
  - a bulkhead, said bulkhead comprising a pump and a reservoir, said reservoir having a reservoir inlet and a reservoir outlet, said reservoir inlet in fluid communication with said external heat exchanger flow channel outlet, said pump having a pump inlet and a pump outlet, said pump inlet in fluid communication with said reservoir outlet for pumping fluid from said reservoir outlet;
  - 20 a second fluid supply line, said second fluid supply line in fluid communication with said pump outlet for receiving fluid pumped out of said pump outlet; and
  - 25 an external fluid source, said external fluid source in fluid communication with said bulkhead.
- 15. The system of Claim 14 wherein said reservoir further comprises at least one fluid level detector.

16. The system of Claim 15 wherein said fluid level detector comprises at least one prism mounted within the reservoir section, at least one optical beam source and at least one optical beam sensor, said source and sensor being mounted on a reusable master control unit adjacent to the prism.

5 17. The system of Claim 15 wherein:

said bulkhead further comprises a chamber comprising a valve, a first chamber inlet in fluid communication with the external fluid source, a second chamber inlet in fluid communication with the reservoir outlet, and a chamber outlet in fluid communication with the pump inlet; said valve having: a first position whereby the first chamber inlet is open, the second chamber inlet is closed and fluid flows from the external fluid source to the pump inlet; and a second position whereby the first chamber inlet is closed, the second chamber inlet is open and fluid flows from the reservoir outlet to the pump inlet; and said fluid level detector is configured to detect a low fluid level and a high fluid level and said detector generates a first signal representing said low level and a second signal representing said high level; and

15 wherein initially the valve is in its first position and is maintained in said first position in response to said first signal thereby allowing fluid to enter reservoir until it reaches said high level and said level detector generates said second signal, and said valve is actuated to its second position.

20 18. The system of Claim 15 wherein said fluid level detector is configured to detect a low fluid level and generates a signal representing said low level, and said pump is responsive to said signal such that said pump stops pumping when said low level is detected.

19. The system of Claim 14 further comprising a pressure regulator, said pressure regulator in fluid communication with said pump outlet for regulating the pressure of fluid pumped from said pump.

20. The system of Claim 14 wherein said first and said second fluid supply line are connected in a circuit through a heat exchange catheter.

21. The system of Claim 15 wherein said at least one fluid level detector comprises:  
a prism mounted in said reservoir, said prism having a diffraction surface;  
a light beam source;

a light beam sensor; and

wherein said prism is configured so that when light beam is directed against said diffraction surface when said diffraction surface is in contact with air, said light beam is reflected to impinge on said light beam sensor and said sensor generates a signal, and  
5 when said diffraction surface is in contact with fluid, said light beam does not reflect to said light beam sensor and said sensor does not generate a signal.

22. A disposable cassette for supplying heat exchange fluid to a heat exchange catheter, said cassette comprising:

an external heat exchanger having an inlet and an outlet;

- 10 a first fluid supply line, said first fluid supply line in fluid communication with said heat exchanger inlet;

a disposable pump head contained in the cassette, said pump head actuated by an electric motor, said pump head having an inlet and an outlet, and said pump inlet in fluid communication with said heat exchanger outlet; and

- 15 a second fluid supply line, said second fluid supply line in fluid communication with said pump outlet for receiving fluid pumped out of said pump outlet.

23. The cassette of Claim 22 wherein said electric motor is controlled by an amplifier controller, said amplifier controller supplying a constant current to said pump head thereby causing said pump head to supply a relatively constant pressure to said fluid in  
20 said second fluid supply line.

24. The cassette of Claim 22 which further comprises a pressure regulator, said pressure regulator being in fluid communication with said pump outlet for regulating the pressure of fluid pumped from said pump.

25. The cassette of Claim 22 wherein said pump head is a cardioid vane pump.

- 25 26. The cassette of Claim 25 wherein said pump head comprises a rotor that is fitted with a vane for moving fluid from the pump, said rotor being positioned in a quasi-cardioid shaped cavity.

27. The cassette of Claim 26 wherein:

(a) said cavity has a circumference, said rotor has a diameter "D", and said

vane has a length "L";

(b) the cavity circumference comprises:

(i) a first arc defined as 330° to 30° and having a radius  $R_1$ ;

(ii) a second arc defined as 150° to 210° and having a radius  $R_2$ ;

(iii) a third arc defined as 30° to 150° and having a radius  $R_3$ ; and

(iv) a fourth arc defined as 210° to 330° and having a radius  $R_4$ ;

(c) wherein all measurements are based upon the center of the rotor and 0° is identified with the point midway between the inlet and the outlet of the cavity; wherein the radii are defined as:

$$R_1 = D/2$$

$$R_2 = L - (D/2)$$

$$R_3 = (D/2) + \{ [(L-D)/2] \cdot [\cos (1.5\theta + 135)] \}$$

$$R_4 = (D/2) + \{ [(L-D)/2] \cdot [\cos (1.5\theta - 315)] \}$$

28. The cassette of Claim 22 wherein said pump head is an impeller pump.

29. The cassette of Claim 22 wherein said pump head a gear pump.

30. A method for providing a temperature regulated source of heat exchange fluid for heat exchange catheters, comprising the steps of:

providing a circuit comprising an external heat exchanger, a pump, a heat exchange catheter, and air vents, said external heat exchanger, pump and heat exchange catheter in fluid communication such that fluid pumped by the pump is circulated through said heat exchange catheter and said external heat exchanger, and said air vents allow passage of gas in and out of said circuit through said vents but do not allow passage of liquid in and out of said circuit through said air vents;

providing a heat generating or removing unit in heat exchange relationship with said external heat exchanger;

providing an external fluid source in fluid communication with said circuit;

circulating heat exchange fluid from said external source through said circuit by means of pumping with said pump while simultaneously venting any gas contained in said circuit out through said air vents; and

controlling the temperature of said heat exchanger fluid in said circuit by controlling the temperature of said heat generating or removing unit.

31. The method of Claim 30 further comprising the steps of:

5 providing a valve between said external fluid source and said circuit, said valve having an open position which permits the flow of heat exchange fluid from said external fluid source into said circuit and a closed position which prevents the flow of heat exchange fluid from said external fluid source to said circuit;

providing a level sensor within said circuit to sense when the fluid level in said circuit is full, said level sensor generating a signal in response to said full fluid level;

10 initially maintaining said valve in said open position until said sensor senses that the fluid level in said circuit is at an adequately full level; and

operating said valve into said closed position in response to said signal.

32. The method of Claim 30 further comprising the step of controlling the pressure of said fluid as said fluid is circulated through said circuit.

- 15 33. The method of Claim 32 wherein said pressure control comprises a pressure regulator in fluid communication with said circuit.

34. The method of Claim 33 wherein said pressure regulator is a pressure damping mechanism.

- 20 35. The method of Claim 32 wherein said pump is operated by an electric motor, and said pressure is controlled by maintaining a predetermined current to said electric motor.

36. A cassette for supplying heat exchange fluid to a heat exchange catheter, said cassette comprising:

25 an external heat exchanger comprising a structural member and a compliant member, said compliant member sealed to said structural member in a pattern, said pattern forming a flow channel between said compliant member and said structural member; said flow channel having an inlet and an outlet;

a first fluid supply line, said first fluid supply line in fluid communication with said flow channel inlet;

a bulkhead, said bulkhead comprising a reservoir and a disposable pump head,

said reservoir containing an inlet in fluid communication with said flow channel outlet, said reservoir further having a fluid level detector for detecting the level of fluid within said reservoir, said pump head being a cardioid vane pump head, said pump head actuated by an electric motor, said pump head having an inlet and an outlet, and said pump inlet in fluid communication with said reservoir outlet said electric motor is controlled by an amplifier controller, said amplifier controller supplying a constant current to said pump head thereby causing said pump head to supply a relatively constant pressure to said fluid in said second fluid supply line;

a second fluid supply line, said second fluid supply line in fluid communication with said pump outlet for receiving fluid pumped out of said pump outlet;

an external fluid source, said external fluid source in fluid communication with said reservoir; and

a pressure damper, said pressure damper in fluid communication with said pump outlet.